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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/690,211

10/21/2003

James Spitler

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DALLAS OFFICE OF FULBRIGHT & JAWORSKI L.L.P.

2200 ROSS AVENUE

SUITE 2800

DALLAS, TX 75201-2784

EXAMINER

HOFFMAN, MARY C

ART UNIT

PAPER NUMBER

3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

12/29/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/690,211	Applicant(s) SPITLER ET AL.	
	Examiner Mary Hoffman	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 20-26, 29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25 is/are allowed.
- 6) ☒ Claim(s) 1-9, 20-24, 26, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/18/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 2, 3 and 20, and dependents thereof, are objected to because of the following informalities:

In claim 2, applicant recites the term "distal end", which has no antecedent basis; however, it appears that applicant had intended to recite "the distal portion" as it currently appears in claim 1. Applicant also recites "distal end" in at least lines 6-7 of claim 3.

In claim 3, line 3, Applicant appears to have inadvertently left out the term -- anchor-- from the end of the phrase "a mating receptacle coupled to the second bone".

In claim 20, line 10, Applicant should change "detachable" to the adverb -- detachably-- to recite the phrase "detachably coupled".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 25 and 29-30 are being interpreted under 35 U.S.C. 112, sixth paragraph. Claim 26, however, is not being interpreted this way because it contains too many structural limitations, e.g. "a pair of bearings...interfacing with the brace by indentations", and therefore does not qualify under 35 U.S.C. 112, sixth paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 26 and 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites the limitation "the supporting means" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 30 recites the limitation "the first and second anchor engagement means" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 7-9 and 20-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Jammet (EP 1072228).

Jammet discloses embodiments of a medical implant system comprising a first bone anchor (ref. #1), a second bone anchor (ref. #2), and a brace (ref. #9/18/16/8) capable of coupling the first bone anchor to the second bone anchor. The brace has a distal portion (ref. #9/18), which is capable of being pivotally [indirectly] coupled to the first bone anchor and adapted to slide in a generally transverse direction in relation to the longitudinal axis [via the threaded rod (ref. #18) connection]. The distal portion of the brace is capable of transferring torque and compressive force from the brace to at least

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one of the bone anchors. The system further comprises a hinge (ref. #E2) attached to a proximal end of the first bone anchor for facilitating the pivotal mating. The hinge is capable of allowing for polyaxial rotation with respect to the first bone anchor. The proximal end of the brace is further capable of accepting torque applied thereto. The system is capable of being used in the vertebrae and the bone anchors are screws capable of being placed in the pedicle of the vertebrae. The hinge comprises proximal and distal openings (ref. #26) in-line from each other forming an in-line passage through the hinge; the distal opening comprising a clamp for rotatable attachment to the head of a bone anchor; the proximal opening capable of accepting the distal end of a brace prior to the bone anchor being secured in a bone, the hinge further comprising a pivot point capable of accepting a captured brace so as to allow the accepted brace to pivot with respect to the hinge but not to become released therefrom; and wherein the clamp allows the distal end of an accepted brace to become detachably coupled to the head of an attached anchor for the purpose of force transfer between the brace and the anchor. The proximal end of the hinge is further capable of accepting a force applying locking structure. The pivot includes at least one pair of bearings (ref. #27) positioned on either side of the in-line passage. The brace comprises a first key (ref. #53) at its distal end capable of releasably mating with a head of a first anchor so as to allow torque transfer between the brace and the first bone anchor; and a second key at its proximal end (ref. #41) capable of being releasably mating with a receptacle at a second one of the bone anchors. The shank further comprises at least one slot (ref. #10) longitudinally displaced along the shank in proximity to the distal end, the slot capable of accepting a fulcrum

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point affixed to the first anchor so as to allow the brace to pivot around the fulcrum point while still maintaining the shank in controlled spatial relationship with the first bone anchor. The brace comprises a curved shank portion (see curved portion, ref. #9).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9 and 20-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Landry et al. (U.S. Patent Application Publication 2004/0138662).

Landry et al. disclose a medical implant system comprising a first bone anchor having a longitudinal axis; a second bone anchor; and a brace for coupling the first bone anchor to the second bone anchor, wherein the brace has a distal portion which is adapted to be pivotally coupled to the first bone anchor and adapted to slide in a generally transverse direction in relation to the longitudinal axis of the first bone anchor (see FIG. 79D/E). The distal portion of the brace is adapted to, i.e capable of, transferring torque and compressive force from the brace to at least one of the bone anchors. The brace further comprises a mating receptacle (ref. #112') coupled to the second bone anchor; and wherein the brace has a proximal end, the proximal end adapted for locking with a the mating receptacle attached to the proximal end of a the second bone anchor, locking occurring when the distal end of the brace pivots with respect to the proximal end of the first bone anchor, the pivoting occurring while the distal portion of the brace remains pivotally mated with the proximal end of the first bone anchor (see FIG. 79E). The receptacle allows for polyaxial rotation with respect to the

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second bone anchor. The receptacle is a force fit with respect to the proximal end of the brace. The receptacle provides positive feedback when the proximal end of said brace is properly mated with the receptacle. The system further comprises a hinge attached to a proximal end of the first bone anchor for facilitating the pivotal mating. The hinge allows for polyaxial rotation with respect to the first bone anchor. The proximal end of the brace is further adapted to accept torque applied thereto. The hinge (ref. #112) comprises proximal and distal openings (top and bottom holes of polyaxial head of bone screw ref. #112) in-line from each other forming an in-line passage through the hinge; the distal opening comprising a clamp (ref. #110) for rotatable attachment to the head of a bone anchor; the proximal opening adapted to accept the distal portion of a brace prior to the bone anchor being secured in a bone, the hinge further comprising a pivot point for capturing an accepted brace so as to allow the accepted brace to pivot with respect to the hinge but not to become released therefrom; and wherein the clamp allows the distal portion of an accepted brace to become detachably coupled to the head of an attached anchor for the purpose of force transfer between the brace and the anchor. The proximal end of the hinge is further adapted to accept a force applying locking structure (set screw, ref. #106).

Response to Arguments

Applicant's arguments filed 09/20/2006 have been fully considered but they are not persuasive.

Applicant believes that the threaded connection formed by the screw-threaded rod ref. #18 cannot be considered to allow the brace "to slide in a generally transverse

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direction in relation to the longitudinal axis” of the first bone anchor. The examiner respectfully disagrees, because the action of screwing and unscrewing the screw-threaded rod can meet this functional limitation, e.g. the distal portion of the brace will slide as the “brace” is expanded due to the unscrewing of the rod (from block ref. #16). Also, since the distal portion, including the screw-threaded rod, is indirectly connected via a ball bearing system to the first bone anchor, it is being considered to be pivotally coupled, even if it may be considered as indirectly coupled. Applicant is reminded that language such as “adapted to” is being considered as functional language, and the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Also see *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). It is the examiner’s opinion that the device of Jammet has the structure necessary rendering it capable of performing the claimed function.

Allowable Subject Matter

Claim 25 is allowed.

The following is a statement of reasons for the indication of allowable subject matter: Applicant is invoking 35 U.S.C. 112, sixth paragraph in claim 25. The prior art

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does not show "a means for transmitting torque between the brace and the at least one of the bone anchors."

Claims 26 and 29-30 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached PTO-892.

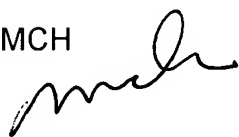
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER